

Office Action Summary

Application No.

10/577,469

Applicant(s)

EL EMAN ET AL.

Examiner

RACHEL L. PORTER

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. This communication is in response to the application filed 4/23/07. Claims 1-20 are pending. See Attached Interview Summary from 5/12/10.

Claim Objections

2. Claim 5 is objected to because of the following informalities: the word need has been misspelled as "need." Appropriate correction is required.

Information Disclosure Statement

3. The IDS's filed 12/28/06 and 2/21/07 have been entered and considered by the Examiner.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-20 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claim 10, the present claim recites "a computer program product containing software..., the software program comprising..." in the preamble. Data structures not embodied on a computer readable media are considered descriptive material. They are therefore considered non-statutory because they are not capable of causing a functional change in a computer. As drafted, the claim fails to define any

structural and functional interrelationships between the code and other elements of a computer that permit the computer program's function to be realized. (See MPEP § 2106.01) Given that there is support in the specification, the claim language should clarify that the software is stored on a (non-transitory) medium.

Claims 11-20 have similar deficiencies and fail to correct the deficiencies of claim 10. Therefore, claims 11-20 are also rejected as being drawn toward non-statutory subject matter.

Claim Rejections - 35 USC § 112, Fourth Paragraph

5. The following is a quotation of that portion of 35 U.S.C. 112 which forms the basis for rejections made under this section in this Office action:

A claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.

6. Claim 9 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph), or, in other words, that it shall not conceivably be infringed by anything which would not also infringe the basic claim.

When, as here, an independent claim recites a particular method, a dependent claim drawn to an apparatus capable of performing the method of the independent claim is not a proper dependent claim, since the dependent claim (the apparatus) could conceivably be infringed by mere possession of the apparatus without performing any

particular method steps at all, thereby infringing the dependent claim (the apparatus) without necessarily infringing the independent claim (the method), in violation of the infringement test for proper dependency of claims. See MPEP § 608.01(n)(III).

Applicant is required to cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 8, 10-17, and 19-20 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by Hotchkiss et al (US 20030140043A1)

[claim 1] Hotchkiss discloses a method comprising the steps of:

- retrieving an XML file from a computer-readable medium, said XML file detailing data and structure of a patient form; (par. 21-24; (par. 125)
- processing said XML file by running of an XML-responsive application; (par. 125)
- generating said patient form defined by said XML file; and (par. 125, 150—registering candidates; par. 154-156—enrollment for studies)

- displaying said patient form on a display. (Fig. 9, 12-13)

[claims 2] Hotchkiss discloses the method according to claim 1, wherein said patient form is a screening form. (Figure 9,12-13, par. 150--gathering patient/candidate data)

[claim 3] Hotchkiss discloses the method according to claim 1, wherein said patient form is a post- randomization form. (par. 166-167; Figure 17--enrolling the patients in the studies)

[claim 4] Hotchkiss discloses the method according to claim 1, wherein said patient form is a termination form. (par. 156; Fig. 13-close enrollment)

[claim 8] Hotchkiss the method according to claim 1, wherein said display is a personal digital assistant display. (Fig. 9, 12-13, par. 74)

[claim 10] Hotchkiss teaches a computer program product containing a software program for installation in a central computer system that is connected to a network, the software program comprising: code for generating code for a patient form, said patient form defined by an XML file. (par. 125, 150—registering candidates; par. 154-156—enrollment for studies)

[claim 11] Hotchkiss teaches the computer program product according to claim 10, wherein said patient form is a clinical trial screening form. (Figure 9,12-13, par. 150--gathering patient/candidate data)

[claim 12] Hotchkiss discloses the computer program product according to claim 10, wherein said patient form is a clinical trial post-randomization form. (par. 166-167; Figure 17--enrolling the patients in the studies)

[claim 13] Hotchkiss discloses the computer program product according to claim 10, wherein said patient form is a clinical trial termination form. (par. 156; Fig. 13—close enrollment)

[claim 14] Hotchkiss discloses the computer program product according to claim 10, wherein said software program further comprises code for network deployment of said code for a patient form. (par. 76, 125)

[claim 15] Hotchkiss discloses The computer program product according to claim 10, further comprising an XML form specification facilitating creation of said patient form. (par. 125, 150, par. 154-156; Figure 1)

[claim 16] Hotchkiss discloses the computer program product according to claim 15, wherein said XML specification includes custom scripting for form events. (par. 76, 125, Figure 1)

[claim 17] Hotchkiss discloses the computer program product according to claim 16, wherein possible responses to a form event include hiding a question within said patient form and revealing a question within said patient form. (par. 150—patient registration questions in patient form; par. 167—questionnaire for criteria)

[claim 19] Hotchkiss discloses the computer program product according to claim 14, further comprising generated code deployable for use in any of an internet information server and an interactive voice response system. (par. 74-77)

[claim 20] Hotchkiss discloses the computer program product according to claim 10, further comprising code for restricting read and edit permissions to control who has what permission in relation to said patient form. (par. 4, par. 6)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 5-7, 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotchkiss et al (US 20030140043A1) in view of Colon et al (US 5991731A).

[claim 5] Hotchkiss discloses the method according to claim 1, further comprising the steps of:

- transmitting need patient information across a communications medium in order to process said patient information when both said patient information has been entered into said patient form and said patient form has been submitted; (par. 166-167)
- using said patient information to verify eligibility of a patient; and (par. 173-175)

Hotchkiss does not expressly disclose the use of a randomization code or routine for the clinical trial. However, as disclosed by Colon randomization routines/codes are well-known for scientific studies (i.e. clinical trial)

Colon discloses a method wherein:

- if eligibility of said patient is confirmed, generating a randomization code for said patient and for use in a clinical trial. (col. 5, lines 15-47)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Hotchkiss with the teaching of Colon to include the use of a randomization code/routine. One would have been motivated to include this feature to minimize any bias introduced into the study, and to allow the randomization to be done automatically, thereby maximizing confidentiality. (col. 1, lines 54-63)

[claim 6] Hotchkiss discloses the method according to claim 5, wherein said patient form is a screening form. (Figure 9, 12-13, par. 150--gathering patient/candidate data)

[claim 7] Hotchkiss discloses a method of providing patient forms, as explained in the rejections of claims 5-6, but does not expressly disclose storing said randomization code in a database within a central computer system.

Colon discloses a method further comprising storing said randomization code in a database within a central computer system. (col. 6, lines 39-52) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Hotchkiss with the teaching of Colon to include the use of a randomization code/routine and to store this information on a central computer. One would have been motivated to include this feature to minimize any bias introduced into

the study, and to allow the randomization to done automatically, thereby maximizing confidentiality. (col. 1, lines 54-63)

[claim 9] Hotchkiss discloses a network comprising a plurality of nodes, one of said nodes being a central computer system, at least another of said nodes being a wirelessly enabled device in communication with said central computer system, at least yet another of said nodes being a personal computer in communication with said central communication system, (par. 73-76). Hotchkiss discloses the method according to claim 1, further comprising the steps of:

- transmitting need patient information across a communications medium in order to process said patient information when both said patient information has been entered into said patient form and said patient form has been submitted; (par. 166-167)
- using said patient information to verify eligibility of a patient; and (par. 173-175)

Hotchkiss does not expressly disclose the use of a randomization code or routine for the clinical trial. However, as disclosed by Colon randomization routines/codes are well-known for scientific studies (i.e. clinical trial)

Colon discloses a method wherein:

- if eligibility of said patient is confirmed, generating a randomization code for said patient and for use in a clinical trial. (col. 5, lines 15-47)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Hotchkiss with the teaching of Colon to include

the use of a randomization code/routine. One would have been motivated to include this feature to minimize any bias introduced into the study, and to allow the randomization to be done automatically, thereby maximizing confidentiality. (col. 1, lines 54-63)

[claim 18] Hotchkiss discloses the program of claim 12 as explained in the rejection of claim 12, but does not expressly disclose the use of randomization codes or routines for the clinical trial. However, as disclosed by Colon randomization routines/codes are well-known for scientific studies (i.e. clinical trial). Colon discloses code for wherein generating a randomization code for said patient and for use in a clinical trial. (col. 5, lines 15-47). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify Hotchkiss with the teaching of Colon to include a randomization code on post-randomization forms for a patient of a clinical trial. One would have been motivated to include this feature to minimize potential population bias introduced into the study. (col. 1, lines 54-63)

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Bleicher et al (US 6820235B1) discloses generating clinical trial forms using SGML derived languages.

- Brooke et al (US 6748569B1) discloses a program and method for generating XML documents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/Robert Morgan/
Primary Examiner, Art Unit 3626

